K081818

510(k) Summary
21 CFR 807.92

NOV 13 2008

Submitter's Name & Address

Manufacturer: BioHorizons Implant Systems, Inc.
2300 Riverchase Center
Birmingham, AL 35244
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Official contact: Michael Davis, Regulatory Affairs Specialist
Date prepared: June 25, 2008

Name of the Device

Trade Name: BioLok Micro-Lok Implant System
Common or Usual Name: Screw-type Dental Implants
Classification Name: Endosseous implants, surgical components, and prosthetic attachments
Classification Number: Class II

Predicate Device

The Minimatic (BioLok International) Various Implant Systems, documented under 510(k) number K952905, concurrence date of April 16, 1997.

Device Description

The BioHorizons BioLok Micro-Lok dental implants are machined titanium, root-form implants supplied in 3.45mm, 3.75mm, 4mm, and 4.75mm diameters across lengths of 8mm, 10mm, 11.5mm, 13mm, and 15mm. Implant and accessory surgical component raw material is titanium alloy as specified in ASTM F136, *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*

The product is packaged using materials known in the industry to be appropriate for medical device packaging and is provided with a minimum sterility assurance level of 10^{-6}, validated in compliance to ANSI/AAMI/ISO 11137, *Sterilization of healthcare products - Requirements for validation and routine control - Radiation Sterilization.*

Intended Use

The intended use of the BioHorizons BioLok Micro-Lok endosseous implants is in the mandible and maxilla as an artificial root structure for single tooth replacement or as abutments for fixed bridgework and denture retention.

Technological Characteristics

The fundamental scientific technology of the device is identical to the referenced predicate device. All materials and specifications (with the exception of the particular ASTM standard titanium specified in the original 510(k) submission), processing and sterilization methods remain the same as for the predicate Minimatic endosseous implants. The material has not changed to a type that has not been used in other legally marketed devices within the same classification regulation for the same intended use. The BioHorizons BioLok Micro-Lok implants are substantially equivalent to all features of the predicate Minimatic (BioLok International) Various Implant System device which could affect safety or effectiveness because of the similarities in design, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2008

Mr. Michael Davis
Regulatory Affairs Specialist
BioHorizons Implant Systems, Incorporated
2300 Riverchase Center
Birmingham, Alabama 35244

Re: K081818
Trade/Device Name: BioLok Micro-Lok Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 10, 2008
Received: October 14, 2008

Dear Mr. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sophie Y. Michaud OMD.

Chiu S. Lin, Ph. D FOR DR. CHIU LIN
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K081818

Device Name: BioLok Micro-Lok Implant System

Indications for Use:

The BioLok Micro-Lok Implant System may be used in edentulous sites for support of a complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework or partial dentures, or a single tooth replacement, overdenture, or hybrid denture.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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